MAY - 5 2011

510(k) Summary – K110358

Submitter Information:

Microtek Medical, Inc.
602 Lehmberg Road
Columbus, Mississippi 39702

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Date Prepared: April 14, 2011

Device Name:

Proprietary name: Microtek Medical, Inc. Venodyne DVT Advantage, 810 Compression System

Common name: Compressible Limb Sleeve Pump

Classification name: Compressible Limb Sleeve Pump, 21 CFR 870.5800

Predicate Devices:

K040511 SCD Express Portable Compression System, Tyco Healthcare/Kendall

K001802 Venodyne Model 610, Microtek Medical, Inc.

K011318 Venodyne DVT Advantage Plus 710, Microtek Medical, Inc.

Description of Device:

The Venodyne DVT Advantage 810 compression system is a microprocessor controlled pneumatic pump that inflates and deflates a set of single chamber leg garments (sleeves) or foot garments (sleeves), which are placed on the patient's lower limbs or feet. During the inflation cycle, the inflatable garments compress the limb or foot along with the veins contained within to a preset pressure. This assists in propelling blood from the lower

limbs or feet towards the heart. During the deflation cycle, the veins are allowed to fill with blood. The cycle is repeated intermittently.

Intended Use:

The Venodyne DVT Advantage 810 venous compression system is an instrument designed to reduce the incidence of venous thromboembolism by preventing the lower limbs or feet aiding the blood flow back toward the heart to help prevent DVT (Deep Vein Thrombosis) in Patients at risk.

Technological Characteristics:

Testing was performed on the proposed Venodyne DVT Advantage 810 compression system to confirm substantial equivalence to the predicate device(s). Testing included Electrical Safety testing according to UL 60601-1, CAN/CSAC22.2 601.-M90, CAN/CSA C22.2 601.1S1-94, and CAN/CSA C22.2 601.1B-98, Radio Disturbance according to EN 55011:2007, Radio Noise Emissions according to FCC part 18 and Electromagnetic Compatibility according to EN 60601-1-2:2007. In addition Verification and Validation testing was performed on general controller features, compression cycle operation, alarm modes, and battery operations. Testing results demonstrate the proposed device is substantially equivalent to the legally marketed predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Microtek Medical, Inc.
c/o Mr. Tom Bonner
Vice President, Regulatory Affairs
602 Lehmberg Road
Columbus, MS 39702

MAY - 5 2011

Re: K110358
Trade/Device Name: Venodyne V810
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: April 18, 2011
Received: April 20, 2011

Dear Mr. Bonner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110358

Device Name: Venodyne DVT Advantage Model 810

Indications For Use:

The Venodyne DVT Advantage 810 is designed to compress the lower limbs aiding the blood flow back toward the heart to prevent DVT (Deep Vein Thrombosis) in patients at risk.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110358